

REMARKS

Claims 3-7, 9-12, 14-23, 25-27, 29-34, 36-42 and 46-54 are presently pending and under consideration. Claims 4, 5, 9, 26, 31, 33, 37, 51 and 52 have been amended herein. No claims have been added or cancelled. **ACKNOWLEDGE DEEMED ALLOWANCE**

Claim 4 has been amended. As amended, claim 4 is directed to the polynucleotide of claim 3, further encompassing SEQ ID NO: 1. The amendment to claim 4 is supported throughout the specification and claims as originally filed, for example, at page 4, lines 24-26.

Claim 5 also has been amended to replace the term “protein” with “Vff2p.” As amended, claim 5 is directed to the polynucleotide of base claim 3, wherein the encoded Vff2p is about 32kD. The amendment to claim 5 is supported throughout the specification and claims as originally filed, for example, at page 5, lines 9-10.

Claim 9 has been amended to correct its dependency and is now dependent on claim 6, rather than on cancelled claim 8. Claim 9 also has been amended to remove the phrase “operably linked to a second promoter,” which is redundant.

Claim 26 also has been amended. As amended, claim 26 is directed to the recombinant host cell of claim 25, wherein the polynucleotide sequence comprises SEQ ID NO: 1. The amendment to claim 26 is supported throughout the specification and claims as originally filed, for example, at page 5, lines 4-12.

Finally, claims 31, 33, 37, 51 and 52 have each been amended herein to recite a positive process step that refers back to the preamble. The amendments are therefore supported by each claim's original preamble.

No new matter is introduced by the amendments to claims 4, 5, 9, 26, 31, 33, 37, 51 and 52. Applicants respectfully request entry of the amendments.

Rejections under 35 U.S.C. § 101

Applicants respectfully traverse the independent rejections of claims 4 and 26 under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. Claim 4, as amended herein, is directed to the polynucleotide of base claim 3, which is not subject to this rejection. Similarly, claim 26 has been amended to recite the recombinant host cell of base claim 25, which is not subject to this rejection.

In view of the amendments to claims 4 and 26, the rejection under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter has been rendered moot and withdrawal is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Applicants respectfully traverse the rejection of claims 3, 5-7, 11, 12, 14, 16-23, 25, 27, 29-34, 36-42 and 46 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

The Office Action alleges that written description is lacking for "conservative variations" of SEQ ID NO: 2 (current Office Action, mailed March 25, 2004, page 5, final paragraph). The Office

provides two Nature papers asserted to show the unpredictability of establishing function based on structural characteristics (current Office Action, mailed March 25, 2004, page 5, first partial paragraph).

Applicants are not required to provide written description for elements not recited in the claims. Applicants note that the Vff2p of the invention is claimed entirely in structural terms and does not rely on functional elements to describe the claimed protein. Rather, the Vff2p is described as SEQ ID NO: 2 or conservative variations thereof. The issue with regard to written description is therefore whether the skilled artisan can envision conservative variations of SEQ ID NO: 2. The specification provides written description for the full scope of the invention.

The specification teaches, for example, at page 10, lines 11-30, that a variant can be prepared, for example, by making a conservative substitution to the amino acid sequence of Vff2p that results in a polypeptide having the same or improved qualities as compared to the native polypeptide. The specification describes at page 9, lines 15-20, that a conserved substitution is a substitution with an amino acid that makes the smallest change possible in the charge of the amino acid or size of the side chain of the amino acid (alternatively, in the size, charge or kind of chemical group within the side chain) such that the overall peptide retains its spatial conformation but has altered biological activity.

The specification further provides written description by teaching that a conservative substitution is the substitution of an amino acid with another amino acid having a similar side chain so as to allow for the overall peptide to retain its spatial conformation. Furthermore, at page 9, lines 20-29, the specification describes additional amino acid substitutions that can be made to a polypeptide of the invention that can result in, for example, increased secretory

properties or enhanced ease of linkage to other molecules. In particular, the specification provides description of common conserved changes as Asp to Glu, Asn or Gln; His to Lys, Arg or Phe; Asn to Gln, Asp or Glu and Ser to Cys, Thr or Gly and, for the purpose of the conserved substitution, describes the 20 essential amino acids as follows: alanine, valine, leucine, isoleucine, proline, phenylalanine, tryptophan and methionine having nonpolar side chains; glycine, serine, threonine, cystine, tyrosine, asparagine and glutamine having uncharged polar side chains; aspartate and glutamate having acidic side chains; and lysine, arginine, and histidine having basic side chains. In addition, at page 10, lines 11-21, the specification provides even further description of the invention polypeptides by teaching that amino acids can be substituted based on consultation of a hydropathicity or hydrophilicity index. In view of these teachings, Applicants respectfully submit that the description provided regarding a Vff2p encompassing SEQ ID NO: 2 and conservative variations thereof allows the skilled artisan to envision conservative variations of SEQ ID NO: 2 and is sufficient to show that Applicants had possession of the invention as claimed.

Applicants maintain that the specification provides sufficient description and guidance to convey to one skilled in the art that Applicants were in possession of the claimed invention. Accordingly Applicants respectfully request that the Examiner remove the rejection of claims 3, 5-7, 11, 12, 14, 16-23, 25, 27, 29-34, 36-42 and 46 under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112, second paragraph

Applicants respectfully traverse the rejection of claims 5, 9, 10, 31, 33, 37, 51 and 52 under 35 U.S.C. § 112, first paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention.

Regarding Claim 5

The Office Action asserts that claim 5 lacks antecedent basis for “the encoded protein” because it is allegedly unclear if the encoded protein in Vff2p or the heterologous target protein. Claim 5 has been amended and is now directed to the polynucleotide of claim 3, wherein the encoded Vff2p is about 32 kD. Accordingly, Applicants respectfully submit that the rejection of claim 5 under 35 U.S.C. § 112, second paragraph, has been rendered moot and request that this ground of rejection be withdrawn.

Regarding Claim 9

The Office Action asserts that claim 9 lacks antecedent basis for “claim 8” because claim 8 had been cancelled previously. Applicants have amended claim 9 to depend on pending claim 6. Accordingly, Applicants respectfully submit that the rejection of claim 9 under 35 U.S.C. § 112, second paragraph, has been rendered moot and request that this ground of rejection be withdrawn.

Regarding Claim 10

Applicants respectfully traverse the rejection of claim 10 as allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention. Applicants request that the Examiner provide the grounds for this rejection so that Applicants may respond. Alternatively, Applicants respectfully request withdrawal of the rejection of claim 10 under 35 U.S.C. § 112, second paragraph.

Regarding Claims 31, 33, 37, 51 and 52

For each of claims 31, 33, 37, 51 and 52, it is asserted that the claim is indefinite for failing to recite a positive process step that refers back to the preamble of the claim. As amended, each of claims 31, 33, 37, 51 and 52 recites a positive process step that refers back to the claim preamble. Accordingly Applicants respectfully submit that the rejection of claims 31, 33, 37, 51 and 52 under 35 U.S.C. § 112, second paragraph, has been rendered moot and request that this ground of rejection be withdrawn.

Rejections under 35 U.S.C. § 102

Applicants respectfully traverse the independent rejections of claim 4 and claim 26 under 35 U.S.C. § 102(b) as allegedly anticipated by *EMBL* entry SCL9476 and Livingstone-Zatchej et al., *Nucleic Acids Res.* 25:3795-3800 (1997), respectively.

Regarding Claim 4

Applicants respectfully submit that this rejection has been rendered moot by the amendment to claim 4, which now depends on claim 3 as its base claim. Accordingly, Applicants respectfully request removal of the rejection of claim 4 under 35 U.S.C. § 102(b) as allegedly anticipated by *EMBL* entry SCL9476.

Regarding Claim 26

Applicants respectfully submit that this rejection has been rendered moot by the amendment to claim 26, which now depends on claim 25 as its base claim and is directed to a recombinant host cell. Accordingly, Applicants respectfully request removal of the rejection of

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claim 26 under 35 U.S.C. §102(b) as allegedly anticipated by Livingstone-Zatchej et al., *Nucleic Acids Res.* 25:3795-3800 (1997).

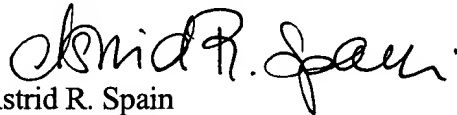
CONCLUSION

In light of the Amendments and Remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to contact the undersigned attorney with any questions related to this application.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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